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PAJUNK® MEDIZINTECHNOLOGIE

# 510(k) Premarket Notification Submission:

## Summary of Safety and Effectiveness

**Date of Preparation: July 20th, 2006**

OCT 13 2006

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**Device Information:**

**Trade Names:** **Veress Cannula and Modular Veress Cannula**
**Common Name**: Veress Insufflation Cannula
**Classification Name**: (reusable) laparoscope, general & plastic surgery
**Classification Reference**: 21 CfR 876.1500
**Poposed Classification:** Regulatory Class: II
**Proposed Product Code:** GCJ, NLM
**Review Panel** General & Plastic Surgery
**Regulation description** Endoscopes and accessories
**Predicate Devices:**

1. Cannula with sharp obturator & Veress Needle by Karl Storz **K800668**
2. Veress Cannula et al. by Richard Wolf Medical **K041321**

**Device Description:**

The insufflation cannulae according Veress were developed especially for the safe and efficient creation of the pneumoperitoneum. All insufflation cannulae are equipped with maintenance free cocks and a female LuerLock connector. Before application, a sharp outer cannula (sterile packed for modular Veress, reusable for Standard Veress) is mounted onto the reusable inner cannula and fastened by means of a LuerLock connector. Therefore within the modular system , a new, absolutely sharp disposable outer cannula is used for every application. In comparison with totally disposable Veress-cannulae, with the same advantages, the modular system offers a large potential to reduce cost.

**Predicate Devices:**

The predicate devices are the Veress cannula of Karl Storz (**K800668**) and the Veress cannula of Richard Wolf (**K041321**). They are found to be substantially equivalent in intended use, indication and technical characterization.

The Pajunk Veress cannula and the Pajunk modular Veress cannula is found to be as safe and effective as and therefore substantial equivalent to the predicate devices.

The detailed discussion of substantial eqivalence can be found in Section 12 of this submission.

**Sterilization**

The **Insufflation cannula according Veress** is supplied non-sterile. It has to be cleaned, disinfected and sterilized before each use by the customer facility according to ist own sterilization protocols.

Cleaning, disinfection and sterilization information for devices supplied non-sterile can be found in section 14.0 of this submission.

The **modular insufflation system acc. Veress** consists of a sterile sharp outer cannula for skin penetration and a reusable or sterile insufflation cannula/ blunt obturator acc. Veress for safe and effective surgical intervention.

The contract sterilizer and the sterilizing process at Sterigenics is the same as that one used for all further Pajunk products already cleared for market in the USA. The Veress cannula is not the worst-case-product which indeed is the Sprotte (**K911221, K911202, K911260**) and the StimuLong Kit (**K043130, K033018**) within Pajunks sterilization process.

**Packaging and Labeling**

The non-sterile Veress insufflation cannula is packaged and labeled just like all the other Pajunks FDA-approved products marketed non-sterile, for example Pajunks Trocar and Balloon Systems **K012771** or Pajunks Handles and Electrodes **K011997, K033249.** Samples and process descriptions for labeling and packaging can be found in section 13.0 and 14.0 of this submission.

**Biocompatibility status**

All materials employed in the manufacturing process that may come in contact with blood, tissue or fluids to be injected have been cleared in Pajunks former 510(k) applications. Furthermore these materials are long term proven materials for the use with medical devices.

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**Indicated Patient population**

The indicated patient population is adult, even though there are several studies for pediatric use.

**Technology Characteristics:**

The inner and outer cannulas consist of stainless steel. Biocompatibility is proven and documented. The outer cannulas guide cone of the reusable Veress as well as the body of the inner cannula consist of brass while the guide cone/ hub of the disposable cannula consists of PC. The sharp outer cannula is intended to penetrate the skin. Then the inner cannula is pushed through and spring locked. Now the pneumoperitoneum can be created by insufflation via the inner cannula.

**Conclusion:**

The comparison between the predicate devices and the proposed devices in section 12 of this submission demonstrates that the proposed devices are safe and effective, as well as substantially equivalent to the predicate devices.

The cannula system acc. Veress has been used for years now. The clinical evaluation and summarizing literature, which is part of this submission (section 10.0), makes this aspects evident.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Christian Quass
Director of Regulatory Affairs
Pajunk GmbH Medizintechnologies
Karl-Hall-Str. 1, 78187 Geisingen
GERMANY

OCT 13 2006

Re: K062097
Trade/Device Name: Veress Cannula and Modular Veress Cannula
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: September 25, 2006
Received: September 27, 2006

Dear Mr. Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for use

**510(k) Number:** K062097

**Device Name:** Veress cannula and Modular Veress Cannula

**Indications for Use:**

The Pajunk insufflation cannula acc. Veress and the modular insufflation cannula acc. Veress is employed in minimal invasive surgery. The cannula is designed for the initial puncture with subsequent gas insuffation for laparoscopic operations. It is used to establish a pneumoperitoneum.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062097

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